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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,595	03/19/2004	Eric W. Rubie	55508-301656	9551

25764 7590 06/06/2008

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2200 WELLS FARGO CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS, MN 55402-3901

EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
06/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,595	RUBIE ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *53* is/are allowed.

6)☒ Claim(s) *1-15, 23-48, 51-52 and 54* is/are rejected.

7)☒ Claim(s) *16-22,49 and 50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-54 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Merlette (US 6,398,818 B1) does not disclose an attachment device mounted on the upper plate. The examiner disagrees. Pylon (14) is vertically extending and is mounted on the upper plate (16). Applicant has not claimed how the components are mounted or attached, therefor an integral attachment meets the claim as the attachment device (14) may be fused or welded to upper plate (16), it is in contact with and extending therefrom thus is mounted on.

The applicant has argued that Allard (US 5,509,937) does not disclose the lower foot plate to comprise a heel portion. The examiner disagrees. Posterior portion of 27a may be considered the "heel portion" as it is located at the rear and where the patient's heel is located. The applicant argues this portion will not contact the ground, however this is not required by the claim. All this is required is a heel *portion*. Any portion need the posterior of the prosthesis supporting the heel may be considered a heel portion.

The applicant has argued that Merlette (US 5,156,631) does not disclose an attachment device mounted on the upper plate. The examiner disagrees. Pylon (11) is vertically extending and is mounted on the upper plate (13). Applicant has not claimed how the components are mounted or attached, therefor an integral attachment meets the claim as the attachment device (11) may be fused or welded to upper plate (13), it is in contact with and extending therefrom thus is mounted on.

The applicant has argued that Pitkin (US 6,290,730 B1) does not disclose a rigid portion on the upper plate. The examiner disagrees. Portion 48 is disclosed to be of a different hardness than plate 16.

The applicant has argued that Wilson (US 5,116,384) does not disclose a sloped upper surface that attaches to the attachment device. The examiner disagrees. Although posterior portion of upper plate (50) may be flat, it is sloped at an angle seen in figs.6a-6c.

The applicant has argued that Phillips (US 5,181,932) does not disclose a lower surface of an attachment device mounted to an upper surface of an upper plate. The examiner disagrees. Lower surface of attachment device is considered the bottom of cylinder 90 seen in fig.5 or bottom of cylinder 30 seen in fig.4. The bottom of cylinder 90 or cylinder 30 is attached (mounted) to the upper surface of upper plate (50; or 50+14). Although upper plate slopes upward to an almost vertical position, it is still curved along its entire length and the plate's entirety may be considered the upper plate (even the upper portion).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-15, 23-24, and 54 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Merlette et al. (US 6,398,818 B1, cited previously). See figures 2-4 particularly. Merlette discloses a prosthesis comprising a lower foot plate (18) and upper foot plate (16) disposed in a generally uniform spaced relationship (fig.1, 2; spaced as *generally* uniform as applicants own figures), the lower plate is at least as long as the upper plate (upper plate is only portion 16; portion 14 is not part of the upper plate), an elastomeric layer (28) and an attachment device (pylon 14) mounted to the upper plate (fused welded made integral with upper plate 16).

Claims 1-4, 10, 11, 14, 25, 34, 39, 42-44, 47, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Allard et al. (US 5,509,937, cited previously). Referring to the claim 1 grouping, Allard discloses a prosthesis comprising a lower plate (27b), upper plate (27a), and an elastomeric layer (25) disposed there between. Allard discloses the lower foot plate to have a forefoot (anterior 27a) and heel portion (posterior 27a; is located at the heel, thus may be considered a heel portion). Allard discloses the elastomeric layer (25) to extend *substantially* over the lower plate (extend completely over portions 24 and 26, thus over substantially the plate). Allard discloses the plates to be *generally uniformly* spaced from one another (thickness of 25 is constant over most of the plate surfaces; see fig.4, 7). Allard has shown the elastomeric layer (25) to extend to the periphery of the plates (see fig.4). Allard discloses the plates to be made of carbon fibers (col.4, lines 1-3).

Referring to the claim 25 grouping, Allard discloses an upper plate (27a) having a sloped upper surface (posterior portion of 27a; see fig.1, 3, 7, wherein the posterior portion is shown to slope slightly inferiorly in fig.1, 3, superiorly in fig.7) and a lower foot plate (27b) having a forefoot (anterior 27b) and heel portion (posterior 27b or 36) and an attachment device (col.3,

lines 55-58) coupled to the upper plate (coupled by screw 35, see fig.3, 4), the attachment device mounted to the sloped upper surface of the upper plate.

Claims 1-4, 10, 11, 14, 15, 23, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Merlette (US 5,156,631, cited previously). Merlette discloses a prosthesis (fig.1) comprising a lower plate (15), upper plate (13), and an elastomeric layer (21) disposed there between. Merlette discloses the elastomeric layer (21) to extend *substantially* over the lower plate (fig.1; disclosed to extend from toe tip backward, col.4, lines 60-64). Merlette discloses the plates to be *generally uniformly* spaced from one another, wherein an anterior portion is uniformly spaced and a posterior portion has increasing spacing (fig.1; constant spacing between upper 13a+14 and lower 19+18 and increasing spacing between 12 and 17; col.4, lines 24-34). Merlette discloses an attachment device (11) mounted on the upper plate (fig.1; is above and in contact with, is integral, thus mounted to at transition section 12) Merlette discloses the plates to be made of high strength fibers (col.4, lines 35-45) and the elastomeric layer to be polyurethane (col.4, lines 56-58).

Claims 25-32, 34, 38-41, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Pitkin et al. (US 6,290,730 B1, cited previously). Pitkin discloses an upper plate (16) having a rigid portion (48), a flexible portion (rest of 16) and sloped surface (entire upper surface has a slope), a lower plate (14) having a forefoot and heel portion (see fig.2, 4), and an attachment device (12) mounted on the sloped upper plate (16) and having an upper surface for attachment to a prosthesis. Pitkin discloses a mounting portion (the horizontal surface top of 22) having a pyramid adapter (26).

Claims 25-28, 33-36, 38-40, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (US 5,116,384, cited previously). Wilson discloses an upper plate (48) having a rigid, flexible and sloped upper surface (portion 50), a lower plate (12) having a forefoot and heel portion (see figs), and an attachment device (32) coupled to the sloped upper plate surface (shown sloped in figs.2, 4, 6). Wilson discloses a horizontal mounting portion (see fig.5, where a portion of adapter 32 is shown flat where pyramid sits). Wilson discloses the attachment device (32) is bonded (by 74; col.5, lines 49-53) and mechanical fastened (by 36) to the plate (48). Wilson discloses a backing component (28+30; see fig.5) on the lower surface of the upper plate (48), the attachment device (32) attaches to the upper plate (48) by a fastener (36) in the backing component (28+30).

Claims 25-27, 29-31, 34-42, 45, 47, and 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips (US 5,181,932). Phillips discloses a upper plate (50; or 50+14) having a sloped upper surface (entire surface of 50 or 14+50 is sloped), a lower plate (12), and an attachment device (30 in fig.4; or attachment embodiment 90 seen in fig.6-8 as an alternative to that shown as 32 in fig.4) coupled to the upper plate (50 or 14+50). Phillips discloses a bottom surface of attachment device (bottom of cylinder 90) mounted to the sloped upper surface of plate (bottom of cylinder 90 is mounted to the upper surface of plate 50 or 14+50) and the attachment device (90) has an upper surface (top of cylinder) that is for connection to a prosthetic component (30). Phillips discloses a backing component (32 in fig.4 or washer or heads of screws 98 in fig.5) and an intermediate elastomeric layer (70) positioned between the upper (50+14) and lower (12) plates. Phillips discloses two opening for fasteners (98; see fig.8).

Phillips attachment device has a weight reducing cutout on the proximal side, chamfer seen on 90 in fig.7 and 8.

Referring to claims 51 and 52, Phillips discloses a curved upper plate (50), a lower plate (12), and an attachment device (attachment embodiment 90 seen in fig.6-8 as an alternative to that shown as 32 in fig.4) and a backing component (14). Phillips discloses an elastomeric layer (70, 72) inbetween the upper and lower plates.

Claims 1, 3, 4, 7, 10, 11, 14, 15, 23-28, 33-35, 38-40, and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips (US 5,800,569, cited previously). Phillips discloses an upper plate (24, 112), lower plate (22, 110), elastomeric layer (26, 114), an attachment device (32) and a backing component (46 in fig.2 or 126 in fig.5). The upper plate may be considered sloped, as it does during movement the slope angle of the upper plate changes, see figs.3a-3d. The sides of the elastomeric layer are convex when compressed also, see figs.3a-3d.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. (US 5,509,937). Allard discloses the prosthesis to have an elastomeric layer (see above), however is silent to mention any specific materials or the thickness of the material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

make the elastomeric layer of polyurethane and have the uniform thickness to be about 2 mm, since it has been held to be within the general skill of a worker in the art to select a known material (polyurethane) on the basis of its suitability (elastomeric) for the intended use as a matter of obvious design choice, *In re Leshin*, 125 USPQ 416, and also since such a dimension would have involved only a mere change in the size of a component (thickness). A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Allowable Subject Matter

Claim 53 is allowed.

Claims 16-22 and 49-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738